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K102520/S2

BD
Helping all people live healthy lives

SPECIAL PREMARKET NOTIFICATION
[510(K)] Summary- BD Nexiva™ Closed IV Catheter System

Submitter:	Becton Dickinson Infusion Therapy Systems, Inc.
Address:	9450 South State Street Sandy, UT 84070
Contact Person:	Justice Alder Specialist, Regulatory Affairs
Telephone Number: **Fax Number:**	801-565-2662 801-565-2749
Date Summary Prepared:	August 30, 2010
Trade Names:	BD Nexiva™ Closed IV Catheter System
Common Name:	Intravascular Catheter
Classification Name:	Intravascular Catheter (FOZ) 880.5200
Unmodified/Predicate Device:	(K032843) BD Nexiva™ Closed IV Catheter System

Description of the device:

The BD Nexiva™ Closed IV Catheter System consists of an over-the needle, peripheral intravascular catheter made from Vialon™ polyurethane, integrated extension tubing with a Y adapter and clamp, BD Q-Syte™ luer access port, and a passive needle-shielding mechanism.

The design of the Nexiva™ IV catheter can be described as a closed system since it protects clinicians from blood exposure during the catheter insertion procedure. Since the needle is withdrawn through a septum that seals after the needle has been removed and both ports of the Y adapter are closed, blood is contained within the Nexiva™ device during catheter insertion. The pressure exerted on the needle as it passes through the septum wipes blood from the needle, further reducing potential blood exposure. The slide clamp on the integrated extension tubing is provided to eliminate blood exposure when the vent plug is replaced with an infusion set connection of a BD Q-Syte™ luer access port.

Intended Use of the BD Nexiva™ Closed IV Catheter System device: [21 CFR Part 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES; General Hospital and Personal Use Therapeutic Devices Sec. 880.5200]

The Nexiva™ intravascular catheter is inserted into a patient's vascular system for a short-term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravascularly. The needle-shielding feature and luer access port, aid in the prevention of needle-stick injuries. Blood is contained within the device during the catheter insertion process aiding in the prevention of blood exposure. This catheter may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.

The 18-22 gauge Nexiva™ catheters are suitable for use with power injectors rated for a maximum of 300 psi when the luer access port(s) is removed and a direct connection is made.

Technological Characteristics Comparison:
The BD Nexiva™ Closed IV Catheter products have the same technological characteristics with no changes in intended use. The subject device has similar design features and materials as the predicate device. The table below shows the design features and material comparisons between the predicate and subject device.

Characteristics	Subject Device	Predicate Device
1. Catheter adapter, tip shield	**Catheter Adapter** - Decreased adapter pocket width to 0.075" for tighter control of adapter retention lock mechanism **Tip Shield** -Decrease V-clip pocket opening to 0.077" for tighter control of V-clip movement when engaged with adapter **Tip Shield** -Scaling of Internal ID through holes to cannula gauge to improve control of cannula to tip shield movement	**Catheter Adapter** -Adapter pocket width set at 0.088" **Tip Shield** -V-clip pocket width set at 0.084" **Tip Shield** -Internal ID holes were generalized to accommodate all cannula gauge sizes
2. Catheter material,	**Catheter material** -Vialon	**Catheter material** - Vialon

Catheter adapter	X40, Radio opaque material **Catheter Adapter**-24Ga ID set to 0.0406" decreased by 0.0004"	X50, Radio opaque material **Catheter Adapter** -24Ga ID 0.0410"
3. Catheter adapter, needle cover	**Catheter Adapter** -needle cover modified to remove bumps, have a straight interference fit and a solid stop feature **Needle Cover** -Length set to 2.26" (0.040" shortened)	**Catheter Adapter** -needle cover interface had 2 bump interference features and a tapered nose **Needle Cover** -Length was 2.30"
4. Extension tubing	**Ext. Tubing** -increased diameters for 18,20 Ga product	**Ext. Tubing** -all gauges microbore tubing
5. Clamp	**Clamp** -pinch clamp	**Clamp** -slide clamp
6. Catheter adapter, Luer adapter	**Catheter Adapter** -tubing junction increased ID for macrobore tubing, optimized for adhesive addition) **Luer Adapter** -tubing junction increased ID for macrobore tubing, optimized for adhesive addition)	**Catheter Adapter** -designed for microbore tubing and solvent bond joint **Luer Adapter** -tubing junction defined with a swedge design
7. Leur adapter	**Luer Adapter** -PCTG "Y" adapter	**Luer Adapter** -PP "Y" adapter
8. Catheter adapter	**Catheter Adapter** -smaller adapter wing structure (confined within overmolded soft wing)	**Catheter Adapter** -large adapter wing structure (confined within overmolded soft wing)
9. Tip shield	**Tip Shield** -improved ergonomic gripping side wall design to prevent user applying force to catheter adapter directly	**Tip Shield** -Straight side wall design
10. Packaging	**Package** -Rigid design	**Package** -Blister package of

	constrained unit package (dispenser, shipper scaled to new unit package)	assembly
11. Straight luer adapter	**Straight Luer Adapter** - added new configuration	**Straight Luer Adapter** -did not exist
12. Vent plug	**Vent Plug** -placed in straight adapter for air venting	**Vent Plug** -placed on "Y" adapter for air venting
13. Q-Syte, Q-Syte Dust Cover, and End Cap	**Q-Syte, Q-Syte Dust Cover and End Cap** -removed for straight configuration	**Q-Syte, Q-Syte Dust Cover and End Cap** -placed on "Y" configuration
14. Cannula	**Cannula** -bump indented into cannula for tip shield retention	**Cannula** -ferrule bound to cannula for tip shield retention
15. Retaining feature	**Retaining Feature** -washer retains cannula "bump" to prevent tip shield removal	**Retaining Feature** -retention plate retains cannula ferrule to prevent tip shield removal
16. V-Clip	**V-Clip** -flag for cannula tip barrier	**V-Clip** -no cannula tip barrier (barrier provided by retention plate)
17. Cannula, Catheter	**Cannula** -ID, OD gauge size increase as ferrule removed **Catheter** -tip resized to cannula gauge increase	**Cannula** -smaller gauge size to accommodate cannula ferrule **Catheter** -tip confirms to cannula gauge size
18. Wedge	**Wedge** -Improved reduced ID wedge design as ferrule was removed from cannula	**Wedge** -larger ID wedge to accommodate cannula ferrule
19. Tip shield	**Tip Shield** -internal ID holes scaled to smaller cannula size	**Tip Shield** -internal ID increased for larger cannula size
20. Grip	**Grip** -internal ID increased for larger cannula size	**Grip** -internal ID holes scaled to smaller cannula size

Nonclinical Tests Support Substantial Equivalence:
The BD Nexiva™ Closed IV Catheter System is composed of material that have been tested in accordance with ANSI/AAMI/ISO 10993-1 2003 (E) standards. The design verification activities, acceptance criterion, and results have been summarized below which demonstrates safety and efficacy of the device.

	Associated Modification	Product Performance Characteristics/Verification Testing	Acceptance Criteria for Product Verification	Result
Launch 1	1	Premature Decouple Force	DPPM < 280	Pass
	2	Catheter Pull Force	DPPM < 60	Pass
	2	Catheter Burst Strength	DPPM < 60	Pass
	2	Catheter Penetration Force	DPPM <1350	Pass
	2	Catheter Drag	DPPM <1350	Pass
	2	Tip Adhesion	DPPM <1350	Pass
	1	System Drag -Cannula Drag	DPPM < 500	Pass
	1	System Drag -Ferrule Retraction Force	DPPM < 500	Pass
	1	Adapter Release Force	DPPM < 500	Pass
	3	Needle Cover Removal	DPPM USL < 18000	Pass
			DPPM LSL < 200000	Pass
Launch 2	4	Flow Rate Label Claim	-20%/+25%, DPPM < 5000	Pass
			-10%/+15%, DPPM < 5000	Pass
	5	Pinch Clamp Fluid Seal	DPPM < 10000	Pass
	5	Pinch Clamp Engagement Disengagement Force	DPPM < 2000	Pass
	8	Wing deflection force	DPPM USL < 2000	Pass
			DPPM LSL < 500	Pass
	6	Bond Strength -Tubing Bond to Adapter	DPPM < 0.1	Pass
	4	Extension Tube Burst Pressure	DPPM < 60	Pass
	10	Unit Package Seal Peel Force	1.33 Cpk	Pass
	10	Seal Width	1.33 Cpk	Pass
	10	Unit PackageMaterial Thickness – Post Formed (Bottom Wed)	1.33 Cpk	Pass
	10	Package Integrity (Water Leak)	0 out of 2301	Pass
	10	Ship Testing (Drop/Vibration)	0 out of 2301	Pass
	7	Y-Adapter Wishbone Loading	DPPM < 0.1	Pass
	7	ISO Liquid Leakage	DPPM < 500	Pass
	7	ISO Air Leakage	DPPM < 500	Pass
	7	ISO Unscrewing Torque	DPPM < 500	Pass
	7	ISO Resistance to Overriding	DPPM < 500	Pass
	7	ISO Thread Separation	DPPM < 500	Pass
	7	Vent Plug Removal Force/Torque	DPPM USL < 6500	Pass
			DPPM LSL <10000	Pass
	7	Q-Syte Removal Torque	DPPM USL < 6500	Pass
			DPPM LSL <10000	Pass

	Associated modification	Product Performance Characteristics/Verification Testing	Acceptance Criteria for Performance Testing	Result
Single Port	11	ISO Thread Seperation -Both Y female luer	DPPM < 500	Pass
	11	ISO Thread Seperation -Straight female luer	DPPM < 500	Pass
	11	ISO Unscrewing Torque -Both Y female luer	DPPM < 500	Pass
	11	ISO Unscrewing Torque -Straight female luer	DPPM < 500	Pass
	11	ISO Resistance to Override -Both Y female luer	DPPM < 500	Pass
	11	ISO Resistance to Override -Straight female luer	DPPM < 500	Pass
	11	ISO Liquid Leakage	DPPM < 500	Pass
	11	ISO Air Leakage	DPPM < 500	Pass
	12	Vent Plug Torque Removal	DPPM USL < 10000	Pass
			DPPM LSL< 20000	Pass
	11	Bond Strength -Tubing Bond to Adapter	DPPM < 60	Pass
	11	Flow Rate Label Claim	-10%/+15%, DPPM < 5000	Pass
Integration	14,15	Proximal Re-exposure	DPPM < 100	Pass
	17	System Drag -Maximum Adhesion Force	DPPM < 1350	Pass
	17	System Drag -Average Drag Force	DPPM < 10,000	Pass
	17	System Drag -Offset Peak Force	DPPM < 2000	Pass
	17	Flow Rate Label Claim	-20%/+25%, DPPM < 5000	Pass
			-10%/+15%, DPPM < 5000	Pass
	17	Minimum Flow	DPPM < 5000	Pass
	17	Flashback	DPPM < 1000	Pass
	17	Cannula Penetration	DPPM < 1350	Pass
	17	Catheter Penetration	DPPM < 1350	Pass
	17,19	Premature Decouple	DPPM < 280	Pass
	20	Needle Hub Pull	DPPM < 500	Pass

Conclusions from Nonclinical Tests:
The BD Nexiva™ Closed IV Catheter System modifications presented in this submission are substantially equivalent to the currently marketed predicate device (K032843). The intended use and technological characteristics of the BD Nexiva™ Closed IV Catheter System product modifications described in this submission have not been altered, and therefore have remained the same since receiving their original 510(k) approval from the FDA.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to or in support of substantial equivalence herein shall be

construed as an admission against interest under the US Patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Justice Alder
Specialist, Regulatory Affairs
Becton Dickinson Infusion Therapy Systems, Incorporated
9450 South State Street
Sandy, Utah 84070

Re: K102520
Trade/Device Name: BD Nexiva™ Closed IV Catheter System
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: December 6, 2010
Received: December 10, 2010

Dear Ms. Alder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

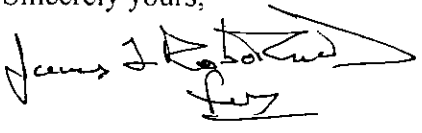
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
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Office of Device Evaluation
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Radiological Health

Enclosure

Becton Dickinson Infusion Therapy Systems, Inc.
Sandy, UT 84070

K102520

INDICATIONS FOR USE

Device Proprietary Name: BD Nexiva™ Closed IV Catheter System

Device Classification Name: Intravascular Catheter (80 FOZ)

Indications for Use:

As indicated in 21 CFR Part 880.5200, The Nexiva™ intravascular catheter is inserted into a patient's vascular system for a short-term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravascularly. The needle-shielding feature and luer access port, aid in the prevention of needle-stick injuries. Blood is contained within the device during the catheter insertion process aiding in the prevention of blood exposure. This catheter may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.

The 18-22 gauge Nexiva™ catheters are suitable for use with power injectors rated for a maximum of 300 psi when the luer access port(s) is removed and a direct connection is made.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: __X____ OR Over-The-Counter Use:_____

Acting for Richard Chapman

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Special 510(k): Device Modification
Indications for Use

510(k) Number: K102520